IN THE UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI
SOUTHERN DIVISION

KRISTIN BERGDOLL and JADE BERGDOLL,	)	
Plaintiffs,	)	
v.	)	**Case No. 6:22-cv-3018-MDH**
COOPERSURGICAL, INC., et al.,	)	
Defendants.	)	

ORDER

Before the Court are the following motions: Plaintiffs' Motions to Exclude Expert Opinion Testimony (Docs. 111 and 113); Plaintiffs' Motion for Partial Summary Judgment on Defendants' Affirmative Defenses (Doc. 115); Defendants' Motions for Summary Judgment (Docs. 117, 119, 121, and 123) and Defendants' Motions to Exclude Expert Opinions and Testimony (Docs. 125, 127 and 129). The motions have been fully briefed and are ripe for review.

Plaintiffs filed this lawsuit for damages under Missouri law based on injuries they allege to have sustained in connection with the use of Filshie Clips, a medical device used in tubal ligations. Plaintiff Kristin Bergdoll underwent a tubal ligation procedure in 2004 in which a Filshie Clip was utilized. Plaintiffs' Complaint alleges claims based on design defect, manufacturing defect, failure to warn, strict liability negligence, violation of consumer protection laws, gross negligence, and punitive damages against the Defendants. In general, Plaintiffs allege the Filshie Clip migrated after the initial procedure causing injury and requiring surgical intervention. Plaintiffs further contend Defendants did not warn or adequately inform Plaintiffs or their healthcare providers about how frequent the migrations occurred, the severity and permanency of potential injuries, and their notice of adverse reports and injuries.

BACKGROUND

The Filshie Clip is a staple-sized, silicone-lined, titanium, occlusive medical device applied laparoscopically and designed to clamp over the fallopian tubes to prevent fertilization and provide female fertility control via tubal ligation. The Filshie Clip is manufactured by Femcare. In 1992, Femcare sought Pre-market Approval ("PMA") for Filshie Clips from the FDA. The Filshie Clip is a Class III Medical Device. In 1996, the FDA determined Filshie Clips to be a safe and effective method of female contraception, granted PMA for the Filshie Clip, and approved the warnings and precautions found in the device's Instructions for Use ("IFU"). The FDA approved warnings and precautions for the Filshie Clip disclosed the potential adverse effects of pain, adverse clip migration at 0.13% based on clinical trials, and asymptomatic migration at an unknown frequency. The Filshie Clip PMA has never been suspended or withdrawn. The design of the Filshie Clip conforms, and has always conformed, to the design submitted to and approved by the FDA in granting PMA for the Filshie Clip. Plaintiffs do not allege any deviation from the FDA's approvide IFU or approved design.

Over the years, Femcare has received patient complaints claiming symptoms related to migration of the Filshie Clip, sometimes called adverse event reports. Pursuant to FDA requirements, Femcare reviews each of these complaints to determine whether it meets the FDA defined threshold for reportability to the FDA. The FDA has reviewed and audited Femcare's complaint-handling procedures and complaint files and has never found non-compliance with its reporting decisions on complaints of clip migration. The Plaintiffs do not dispute this fact. However, Plaintiffs claim the FDA does not know about the vast number of "scientific articles" and "hundreds of adverse event reports" that Defendants have deemed not reportable. In essence,

Plaintiffs contend Defendants are failing to report information to the FDA and if the FDA had this information Defendants would not be in found in compliance.

Plaintiff Kristin Bergdoll underwent tubal ligation using Filshie Clips in 2004. The Filshie Clip IFU in use at the time of her surgery contained the same warnings as those approved by the FDA with the PMA approval. Specifically, that IFU contained the following warnings and instructions:

> Clip Expulsion, Foreign Body Reactions, and Asymptomatic Migration
>
> Instances of clip expulsion per urethra, vaginal cuff and bowel, as well as foreign body reactions have been reported (3 expulsion and 2 foreign body reactions were reported in 5,326 women). Three instances of apparently asymptomatic migration of the clip were observed as incidental findings, but the frequency of this event is not known.
>
> Patient Counseling
>
> Prior to any sterilization procedure being performed, the patient should be fully informed about alternative methods of contraception, the possible side effects of the procedure, any complications which may arise during and following the procedure and the risks and benefits associated with sterilization in general and the Filshie Clip procedure in particular. The patient should fully understand that this is a permanent procedure. In addition, the patient should be encouraged to discuss openly and fully any questions she may have concerning the Filshie Clip.
>
> ADVERSE EFFECTS
>
> The following adverse effects have been reported with the use of the Filshie Clip (see Table 1).
>
> Pregnancy (0.46%); ectopic pregnancy (0.016%); clip migration or expulsion (0.13%); misapplication to ovarian ligament, broad ligament, mentum, bowel, tubal serosa, cornual or broad ligament (0.05%); pain and cramping (35.7%).

In 2021, the FDA approved a Femcare-updated IFU that continues to disclose the adverse migration rate of 0.13% (based on clinical trials). The IFU clarifies that "adverse" means "symptomatic." At no time during this updating process did the FDA require that the IFU disclose

a migration rate of 25%. Plaintiffs allege that Femcare never properly disclosed the alleged 25% migration rate to the FDA and that is why the FDA never required them to change their IFU.

In October 2021, Plaintiffs were informed the Filshie Clips used in Ms. Bergdoll's procedure had migrated and were displaced. Plaintiffs claim she suffered adverse symptoms related to the clip migration. Finally, Plaintiffs also claim the discovery rule should be applied to toll the running of the statute of limitations in this case. Plaintiffs plead that the statute of limitations should not run until Plaintiffs knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that the Plaintiffs had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury. Plaintiffs' complaint alleges that "despite diligent investigation by Plaintiffs of the cause of their injuries, the nature of Plaintiffs' injuries and damages and their relation to Filshie Clips and Defendants' wrongful conduct was not discovered and could not have been discovered, until a date within the applicable statute of limitations." Specifically, Plaintiffs allege Defendants caused a knowing and active concealment and denial of material facts they had a duty to disclose and that it was Defendants' purposeful and fraudulent acts of concealment that kept Plaintiffs ignorant of vital information essential to the pursuit of their claims.

The Cooper Companies, Inc.[1]

TCC is incorporated in the State of Delaware and has its principal place of business in California. TCC states it did not develop, manufacture, sell, or market the Filshie Clips allegedly used by Plaintiffs. TCC contends it did not design, research, conduct safety surveillance for,

[1] TCC and Utah Medical also join in Femcare and Coopersurgical's Motions for Summary Judgment.

develop, manufacture, test, label, package, distribute, market, or sell Filshie Clips at any time or any place.

TCC is the parent corporation of Cooper Medical, Inc. Cooper Medical, Inc., in turn, is the parent corporation of CooperSurgical, Inc. TCC is a corporate legal entity separate and distinct from CooperSurgical, Inc.

In addition to the arguments made by Femcare and CooperSurgical, TCC argues TCC did not design, manufacture, or sell the clips used by Plaintiffs and that TCC is not the alter ego of CooperSurgical and is a separate and distinct corporation.

Utah Medical

Utah Medical is a Utah-based medical device company. In 2011, it acquired Femcare Group Ltd., of which Defendant Femcare Ltd. is a subsidiary. Femcare Ltd. is a corporate legal entity separate and distinct from Utah Medical, organized under the laws of the United Kingdom and with its headquarters in Romsey, County of Hampshire, England. Distinct from Utah Medical's role as the parent company of Femcare, in 2019, Utah Medical became Femcare's exclusive U.S. distributor for the Filshie Clip, having acquired the distributorship rights from CooperSurgical, Inc.

Prior to 2019, Utah Medical did not design, manufacture, import, or distribute Filshie Clips, and thus had no role in the chain of commerce of the product. Only after acquiring the distributorship in 2019 did Utah Medical begin distributing the Filshie Clips in the U.S. In 2004, when Ms. Bergdoll underwent the tubal ligation, Utah Medical had no affiliation with Femcare or with Filshie Clips. It was not until seven years later that Utah Medical became the parent of Femcare Group Ltd.

Utah Medical's role as Filshie Clip distributor post-dates Ms. Bergdoll's tubal ligation by fifteen years. Utah Medical did not develop, design, manufacture, import, market, or distribute the Filshie Clips that are the subject of Plaintiffs' complaint. Rather, Femcare developed, designed, and was the legal manufacturer of Filshie Clips, and CooperSurgical imported, marketed, and distributed Filshie Clips in the United States.

In addition to the arguments made by Femcare and CooperSurgical, Utah Medical argues it did not design, manufacture, or sell Plaintiffs' Filshie Clips and it is not an alter ego of Femcare. It states it is a separate and distinct corporation that did not become a parent of Femcare until seven years after Ms. Bergdoll's surgery.

STANDARD OF REVIEW

Summary judgment is proper where there is "no genuine dispute as to any material fact, and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). "The plain language" of the Rule "mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). "By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986) (emphasis in original). A genuine issue of material fact only exists if a reasonable factfinder could return a verdict for the non-moving party. *Id.* at 248. "On a motion for summary judgment, 'facts must be viewed in the light most favorable to the nonmoving party only if there is a 'genuine' dispute as to those facts.'" *Ricci v. DeStefano,* 557 U.S. 557, 586 (2009) (quoting *Scott v. Harris,* 550 U.S. 372, 380 (2007)).

DISCUSSION

The Filshie Clip is a Class III Medical Device approved by the FDA's Premarket Approval ("PMA") process. Defendants contend that Plaintiffs' claims for injuries related to a device approved through the PMA process are preempted by the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act ("FDCA"). Citing *Riegel v. Medtronic, Inc*., 552 U.S. 312, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). For the reasons stated herein, the Court agrees.

The MDA, 21 U.S.C. § 360c *et seq*., provides the FDA the authority to regulate medical devices. The FDA classifies medical devices into three categories, depending on the level of risk presented. Class III is in the highest category of risk. *Id.* at 316–17; 21 U.S.C. § 360c(a)(1). Class III devices are required to undergo the FDA's premarket approval process which reviews the medical device's safety and effectiveness and prevents a manufacturer from making post-approval changes without the FDA's consent. See *Id.* at 317–20; 21 C.F.R. § 814.1; 21 U.S.C. § 360e(d)(5)(A)(i).

"Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319; citing 21 U.S.C. § 360e(d)(6)(A)(i). Additionally, after PMA approval devices are subject to ongoing reporting requirements, such as informing the FDA of scientific studies on the device and incidents where the device causes death or serious injury. *Id.*; 21 C.F.R. §§ 814.84(b)(2), 803.50(a). The FDA retains authority to withdraw its approval based on this information. *Id.* at 319-20; 21 C.F.R. § 360e(e)(1).

To ensure that FDA oversight is not undermined by state law, the MDA includes an express

preemption provision. 21 U.S.C. § 360k(a). Under this statute, a claim is preempted if a two-part test is met:

> First, a court must determine whether the Federal Government has established requirements applicable to a particular device. Second, the court must determine whether a plaintiff's claims are based upon [state] requirements with respect to the device that are different from, or in addition to the federal ones, and that relate to safety and effectiveness. If the Court answers both questions in the affirmative, the state laws are expressly preempted by the MDA.

Sullivan v. Medtronic, Inc., 498 F. Supp. 3d 1106, 1112 (E.D. Mo. 2020) (citing *Riegel*, 522 U.S. at 321-23).

The MDA also contains an implied preemption provision. 21 U.S.C. § 337(a). That provision states that all actions to enforce FDA requirements "shall be by and in the name of the United States." This provision prohibits suits by private litigants for noncompliance with FDA requirements. *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 349 n. 4 (2001). A parallel state claim is impliedly preempted where it exists solely by virtue of the federal requirements. *Zaccarello v. Medtronic,* 38 F.Supp. 3d 1061, 1066 (W.D. Mo. 2014) (citing *Buckman*, 531 U.S. at 353). "Thus, a state law claim is impliedly preempted when it 'exist[s] solely by virtue' of a federal requirement." *Blankenship v. Medtronic, Inc*., 6 F. Supp. 3d 979, 986 (E.D. Mo. 2014) (citing *Buckman*, 531 U.S. at 353).

The Eighth Circuit has stated:

> *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that violates the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing because the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*).

In In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (internal citations omitted). Claims that Defendants have failed to report, or claims referred to as "fraud-on-the-FDA," that are based on a theory that Defendants committed fraud to allow

their product to be marketed are preempted under the applicable law. *Buckman,* 531 U.S. at 351-53.

It is undisputed that the Filshie Clip was approved through the PMA process. "Premarket approval is a federal requirement that meets the first prong of the test for preemption. *Riegel*, 552 U.S. at 323. As to the second condition, "included in the meaning of 'state requirements' subject to federal preemption are common law causes of action, such as negligence and strict liability." *Id*. at 323-24.

Here, Plaintiffs' claims of manufacturing and design defect attempt to impose responsibilities on Defendants that are different from, or in addition to, the federal requirements. Plaintiffs do not allege, or provide evidence, that Defendants were manufacturing or designing the Filshie Clips in violation of what was required by the FDA's authorization.

The essence of each of Plaintiffs' state law claims is that Defendants failed to comply with the FDA requirements or failed to disclose information to the FDA regarding the product. This is precisely the type of claim that is preempted. The MDA prohibits suits by private litigants for noncompliance with FDA requirements. This includes allegations that Defendants failed to report information to the FDA that would have changed their "approved" product. Plaintiffs allege:

> throughout the years, Defendants have received many adverse event reports where women have suffered serious injuries. However, virtually none of these adverse events were reported to the FDA. In fact, Femcare's director and UTMD's CEO admits that no complaints have been considered reportable under the FDA's guidelines for injury.

In addition, Plaintiffs allege Femcare first applied for FDA approval for distribution in the United States, it reported that the Filshie Clips had a .13% migration rate. On or around 2002, Dr. Marcus Filshie, the inventor of the Filshie Clip, published an article in a scientific publication which stated that the migration rate is 25 percent. Plaintiffs further contend throughout the years,

there are numerous scientific articles and reports that published information about Filshie Clip migration and the damages they can cause.[2] Plaintiffs argue despite the reporting regulations, a vast majority of adverse reports or scientific articles went unreported by the Defendants and as a result women, their medical providers, the FDA, and the public, do not know the true risks of using this product. These claims are preempted as set forth herein.

In *Reigel,* the Supreme Court stated "since the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable ... to the device' under federal law, the Court must first determine whether the Federal Government has established requirements applicable to the medical device. *Id.* at 321. If so, the Court must then determine whether Plaintiffs' common-law claims are based upon state law requirements with respect to the device that are "different from, or in addition to," the federal ones, and that relate to safety and effectiveness. *Id.*

Design and Manufacturing Defect

Plaintiffs have not alleged, nor provided evidence, that the design of the Filshie Clip deviated from the design that was approved by the FDA. As held by the Eighth Circuit: "Absent concrete allegations that the product sold by [defendant] was not the product design approved in the PMA Supplement, these are not parallel claims. Rather, they are attacks on the risk/benefit analysis that led the FDA to approve an inherently dangerous Class III device. Such claims are expressly preempted by § 360k." *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig*., 623 F.3d at 1206 (citations omitted); see also *Zaccarello v. Medtronic, Inc*., 38 F. Supp. at 1061 ("Plaintiff does not allege the design of Infuse deviates from the design approved by the FDA.

[2] Plaintiffs reference requirements imposed in Canada and Australia regarding Filshie Clips. However, this does not change the FDA's requirements that apply in this case.

Therefore, Plaintiff's design defect claim is attempting to impose responsibilities on Defendants that are different from, or in addition to, the federal requirements"); and *Blankenship v. Medtronic, Inc*., 6 F. Supp. 3d at 989.

It is undisputed that the Filshie Clip was studied and approved by the FDA through the PMA process, the Filshie Clip design was approved by the FDA, and the design has not deviated from that approval. Plaintiffs have not provided evidence of a deviation from the FDA design and have not provided expert testimony of any alleged failure to comply with the FDA's requirements. As a result, the design defect claim is preempted.

This same analysis applies a manufacturing defect claim. Plaintiffs have not alleged or shown the Filshie Clip was manufactured in a way that violated the PMA requirements and Plaintiffs' claims are preempted.

Failure to Warn

Plaintiffs' failure to warn claims stem from: 1) allegations that Defendants should have included more extensive warnings about the dangers of Filshie Clip migration (a purported 25% migration rate) and 2) that Defendants failed to report certain complaints and adverse events to the FDA. While the Court will not reiterate the entirety of Plaintiffs' allegations, these two issues are the focus of Plaintiffs' claims against Defendants and the subject of the experts' testimony. Importantly, Plaintiffs do not allege that Defendants deviated from the warnings that were approved by the FDA or that they failed to adhere to the language approved by the FDA.

In *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig*., the Eighth Circuit held "Plaintiffs did not allege that [defendant] modified or failed to include FDA-approved warnings. Rather, they alleged that, by reason of state law, [defendant] was required to give additional warnings, precisely the type of state requirement that is 'different from or in addition to' the federal

requirement and therefore preempted." 623 F.3d at 1205–06. This same finding was set forth in *Blankenship v. Medtronic, Inc*., 6 F. Supp. 3d at 988– 89. In essence when Plaintiffs' claim seeks to impose on Defendants labeling or warning requirements that go beyond what federal law requires any such claims are preempted.

Here, Plaintiffs do not allege that the Filshie Clip's warnings deviated from the language approved by the FDA. By alleging that the Filshie Clip's warnings were inadequate, even though the FDA approved those warnings, Plaintiffs seek to hold Defendants to standards that are different from, or in addition to, the federal requirements and any such claim is preempted. The FDA has approved the IFU and there is no evidence that Defendants have used language that was not approved or that they deviated from the FDA approved language.

In addition, Plaintiffs' claims that "Defendants essentially robbed the FDA of the opportunity to ensure that the labeling on the Filshie Clips were up-to-date and accurate," including the allegation that Defendants never reported a journal article containing the estimate of a 25% asymptomatic migration rate, are also preempted. Similar failure to report claims have been found to be preempted as an attempt to privately enforce FDA requirements. See *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig*., 623 F.3d at 1205-06. As a result, the Court finds Plaintiffs claims that Defendants somehow failed to provide information to the FDA, including adverse events or migration publications, are preempted. See *Blankenship v. Medtronic, Inc.*, 6 F. Supp. 3d at 988–89 ("Furthermore, even if plaintiff based this claim on Medtronic's failure to file an adverse event report with the FDA, the Eighth Circuit has held that such a claim is preempted under *Buckman*"); *Zaccarello v. Medtronic, Inc.,* 38 F. Supp. 3d at 1068, n.2 ("To the extent Plaintiff bases this claim on Defendants' alleged failure to file an adverse event report with the FDA, the claim is impliedly preempted"); and *Antonacci v. Allergan USA, Inc.*, No. 4:20-CV-

001841 AGF, 2021 WL 3404024, at *3–4 (E.D. Mo. Aug. 4, 2021) (finding Plaintiff's claims are preempted pursuant to *Buckman*).[3] For the reasons stated herein the claims are preempted.

Plaintiffs' Claims of Strict Liability, Negligence and Strict Negligence

Plaintiffs' claims for strict liability, negligence and strict negligence are based on the same allegations and theories the Court has already addressed. These claims are also preempted for the reasons stated herein.

Consumer Protection Laws

Plaintiffs' sixth cause of action is for violation of consumer protection laws. While Plaintiffs do not cite or reference the Missouri Merchandising and Practices Act, Defendants cite to *Antonacci,* 2021 WL 3404024 (E.D. Mo. Aug. 4, 2021), that states:

> Plaintiff contends Defendants violated the [MMPA] because they 'concealed the true risks of the Natrelle style breast implants.'. . . Plaintiff's allegations that the Allergan Defendants failed to warn her of the true risks of the Natrelle style breast implants would require a finding that the FDA's approved labelling was inadequate because it did not contain a sufficient warning. This claim, much like Plaintiff's other claims, essentially alleges the Allergan Defendants failed to provide warnings outside those required by the FDA and is therefore preempted.

Plaintiffs' claim for violation of consumer protection laws is based on the same allegations the Court has already discussed. For the same reasons set forth herein, this claim is also preempted.

Additional Arguments

Defendants raise additional arguments regarding jurisdiction, the statute of limitations, causation, failure to provide evidence of damages, failure to establish alter ego and other defenses. However, the Court finds that preemption is dispositive of Plaintiffs' claims and as a result finds analysis of any additional arguments unnecessary.

[3] The Court also agrees with Defendants' argument that this claim is expressly preempted because a Missouri law claim that Defendants had a duty to warn the ultimate user of the products would differ from or add to the federal regulations which require Defendants to report to the FDA.

CONCLUSION

Wherefore, for the reasons set forth herein, the Court finds Plaintiffs' claims are preempted. The Court hereby **GRANTS** Defendants' Motions for Summary Judgment (Docs. 117, 119, 121, and 123) on the issues of preemption as specifically stated herein. The Court **DENIES AS MOOT** Plaintiffs' Motions to Exclude Expert Opinion Testimony (Docs. 111 and 113); Plaintiffs' Motion for Partial Summary Judgment on Defendants' Affirmative Defenses (Doc. 115); and Defendants' Motions to Exclude Expert Opinions and Testimony (Docs. 125, 127 and 129).

IT IS SO ORDERED.

Date: March 4, 2025

/s/Douglas Harpool
Douglas Harpool
U.S. District Judge